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09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/702,037	WHYTE, PETER BENNETT DUFF	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-39,46-48,74 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-39, 46-48 and 74-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-39, 46-48 and 74-75 are presented for examination on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 10, 2007 has been entered.

Response to Amendment

The amendment filed September, 2007 and extension of time have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Austraila on April 30, 1998. It is noted that applicant has filed on June 5, 2006, a certified copy of the patent application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-39, 46-48 and 74-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-39, 46-48 and 74-75 are rendered vague and indefinite for the recitation of the term "significantly" because it is unclear what change in concentrations of IGF-1 is intended. The term is subjective and not recommended for use in the claims and it is suggested that the term be deleted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-39, 46-48 and 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO/97/16977, AU-A-631136/94, , Clark et al, and Ballard et al (US 6,319,522), all cited of record in previous Office action of November 16, 2005.

Claims are drawn to methods of administering colostrum of which is prepared by ultrafiltration and spray drying, and also centrifugation and reconstituting steps can be employed for the preparation of the colostrum. Each of the methods employ administering colostrum for changing physical work capacity of a subject.

WO 97/16977 (WO) teach administering effective amounts of compositions containing colostrum, see abstract and page 21, last two lines. Administering is carried

out over a period of two weeks, see results of sample times, pages 10-12, Tables 3-6. The administering includes ingestion of a food composition (i.e. yogurt, see page 2, line 1) by a subject (i.e. coffee milk composition administered to a subject, see page 14, lines 5-20). The steps of preparing the colostrum are disclosed to encompass centrifugation to reduce bacteria (page 3, line 4), ultrafiltration (page 4, line 5), The colostrum is prepared so as to retain the immunoglobulin fraction containing antibodies and/or growth factors (see the abstract). The centrifugation is disclosed to take place at a temperature between 55 ° C to 63 ° C, (see page 3, lines 12-14). A heating step is disclosed at temperature between 55 ° C to 63 ° C (see page 3, lines 25-26). An effective amount is administered (page 21, line 31) and 12,500 grams is generated, (page 18, line 18).

AU-A-63136/94 (AU) teaches a colostrum product prepared by a method comprising subjecting colostrum to ultra-filtration to obtain an ultra-filtered colostrum retentate, and recovering the retentate, wherein said product is further subjected to a spray drying process. Note page 1 and claim 1 of the this cited patent. Also the colostrum is subjected to bacterial reduction using centrifugation. Note page 1, claim 2. The colostrum is also subjected to heat, note page 4, line 31. Temperatures used and disclosed for preparing the colostrum are less than 64 °C and 72 °C, see page 6, line 15. The colostrum product contains 71.0 % protein, see Table 3.

Clarke et al teach colostrum contains IGF-1 (insulin growth factor-1) proteins, at column 44, 1rd paragraph, lines 11-12. Further, improved body composition and condition is achieved by the presence of IGF-I levels, administered via colostrum note

page 44, lines 1-20. Also reduction of muscle damage during exercise by enhancing healing is disclosed, see page 44-45, all lines and page 46, lines 22-35. Further, it is also disclosed that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue, note page 51 , lines 1-3. Also improved exercise performance is noted in that it is disclosed that physical stress from exercise causes fatique, infection, etc. and colostrum reduces these symptoms and infections, note column 44, second paragraph, lines 6-10. Clarke et al also teach that the effectiveness of colostrum depends on how it is produced or processed, note column 15, lines 6-8.

Ballard et al teach reconstituting dry samples in a buffered saline, note column 26, lines 65-67. Colostrum is disclosed at column 27, line 55.

Claims differ from WO 97/16977 (WO) in that a spray drying step and changing physical work capacity of the subject upon administering the prepared colostrum are not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the above teachings as disclosed to spray dry to prepare the colostrum and then administer it to a subject to change the physical work capacity of the subject disclosed by WO since AU, Clarke et al and Ballard each teach preparing colostrum and AU specifically teaches success for such colostrum preparations using spray drying and Clarke et al teach that colostrum can be processed to enhance the presence of proteins and can include IGF-1. Ballard et al specifically teach preparing colostrum to include a reconsitution step. Therefore, to include other

steps in the process of preparing colostrum as disclosed by WO is clearly within the skill of an ordinary artisan. WO specifically states that other steps may also be included in the process of their disclosure, note page 3, lines 30-32.

Each of the process steps of spray drying and reconstituting colostrum not specifically disclsoed by WO can be performed as recongized by the cited prior art on colostrum with successful expected results. The temperature of centrifugation and heating steps is clearly taught by WO as discussed above. To remove bacteria or reduce bacteria by centrfugation to increase proteins in the colostrum product is clearly taught as well. Ultrafiltration is clearly disclosed. Spray drying is also a recognized step in the art to be performed with success when desired.

Thus, there is no unexpected successful result obtained by Applicants claimed method of preparation. The colostrum would have been expected to have IGF-1 factor and hence would have been expected to be successful for changing physical work capacity of a subject upon adminsitering it to a subject as a food. Each of these claim features are disclosed by the cited prior art as discussed above. Clarke et al recognized that resistive exercise can be changed by reducing infection and fatigue via administering colostrum as a food to a subject in need of such change or repair. Colostrum having IGF-1 clearly would have provided successful results and based upon the teachings of the cited prior art one of skill would have been motivated to administer it to a subject in need of changing work capacity.

To select for specific effective amounts of at least 0.5 g/g/day or from 1 to 10 g/kg/day for a subject to ingest is within the skill of an ordinary artisan. WO teaches that

more than these dosage amounts are obtained from the process, therefore, the dosages as claimed are certainly available in the cited prior art and to determine effective amounts from what is available is well within the purview of a skilled artisan. In the absence to the contrary the claims are rendered *prima facie* obvious.

Response to Arguments

In response to Applicants arguments submitted September 10, 2007, referencing the arguments at pages of 5 to 11 their previous response, the prior art (specifically Clark et al) do teach that proper nutritional intake and IgF-1 levels be maintained to achieve weight reduction and improved body condition, note page 44, lines 1-3. Furthermore, colostrum is taught to be a replacment source of IgF in the body. These teachings suggest that body mass and stature can be monitored to observe change in the physical work capacity of a subject.

Therefore, contrary to Applicant's argument that a prima facie case of obviousness has not been presented, the prior art do suggest or teach each of the claim limitations and the art is combined to show that there is indeed motivation to change physical work capacity of a subject by the subject ingesting a food composition containing a colostrum fraction and the art clearly teaches and recognizes how such fractions are prepared. For these reasons and those record the claims remain rejected over the cited prior art. Also the affidavit is noted but there is an expectation of successful results to replace IgF with a colostrum fraction if so desired and calculated results are not reflected in the instant claims. No unexpected successful results have been obtained based upon a reading of the cited prior art.

To prepare a colostrum fraction is well recognized and to ingest it for improving the physical work capacity of a subject is also suggested. Also Applicants argue features which are not claimed such as human IgF 1. The new claim added would be rejected possibly under 35 USC 112, second paragraph and over the prior art rejection of record because because monitoring body mass and stature is clearly suggested by Clark et al, as discussed above. Thus, although the new claim is deemed by the Examiner to possibly introduce a new issue under 35 USC 112, second paragraph, she decided it would be prudent to allow its entry after final because the art of record does read on the new claim as well in terms of monitoring body mass and stature of a subject. However, the Examiner did not permit entry of the affidavit because the affidavit is not directed to the amounts as claimed and Applicants did not provide a showing of good and sufficient reasons why the calculated results of current technology are needed because these amounts are not being claimed, and further Applicant also did not show a good and sufficient reason why the affidavit was not presented earlier.

Changing physical work capacity is defined as including any exercise performance, recovery after excercise and reduction of fatigue, according to Applicants' own specification at page 3. The argument that Clarke et al does not disclose this is not persuasive because Clarke et al teach colostrum contains IGF-1 (insulin growth factor-1) proteins, at column 44, 1rd paragraph, lines 11-12. Further, improved body composition and condition is achieved by the presence of IGF-I levels, administered via colostrum note page 44, lines 1-20. Also reduction of muscle damage during exercise by enhancing healing is disclosed, see page 44-45, all lines and page 46, lines 22-35.

Further, it is also disclosed that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue, note page 51 , lines 1-3. Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e.,how to monitor changes in physical work capacity, and results of performance of endurance by athletes, and power and strength of athletes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Also the argument that Clarke et al teach away is noted, however, it is not convincing because the preparation of Clarke et al includes proteins and immunoglobulins of which may include IGF-1 and others. The preparations of WO and AU also contain proteins and it would have been well within the purview of an ordinary artisan to include IGF-1 as one of skill would have been led by Clarke et al to provide using the method steps of WO and AU and Ballard et al. Furthermore, Clarke et al do not omit the steps used by WO, AU and Ballard et al by recitation of any negative teaching that these steps would not have led to a colostrum containing proteins, such as IGF-1. Furtther, the instant claims, with one exception, are not so limited to any type of IGF. Ballard et al clearly teach that ease of preparation is desirable, see column 11, lines 34-36 and 43. There is a close association between the simplicity of preparation and colostrum so prepared having IGF-1, and this close association is recognized by the cited prior art.

Furthermore, AU clearly recognizes ultrafiltration and spray drying as well known steps for colostrum preparation which are hardly difficult to perform or considered to render a highly processed colostrum void of IGF-1 or other proteinaceous growth factors. The point that the colostrum prepared and used according to the claimed invention not being homogenized is noted, however, the claims do not omit a homogenizing step and further the first two prior art references cited for their teaching of the claimed method steps do not include homogenizing either.

Also, applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Spray drying is dislcosed by AU and Ballard et al is cited for its teaching of reconstitution step not for its freeze drying step. Also Applicants do not necessarily omit freeze drying from their claims.

WO specifically states that any other process steps so desired may be used. Applicants' claims do not omit the use of other art recognized process steps as disclosed. Each of the claimed process steps and method steps for changing physical work capacity of a subject are disclosed by the cited prior art and one of skill would have been motivated to use them to prepare a colostrum for adminsitering in a food to a subject for reducing fatigue or healing an infection resulting from physical stress as caused by exercise.

Thus, there is no reason one of skill in the art would not expect successful results when the colostrum is subjected to centrifugation, ultrafiltration, spray drying and reconstitution as it is in the instantly claimed subject matter. There is at least a clear suggestion, if not teaching, for administering the colostrum so prepared to a subject for changing the work capacity. Applicants have not shown any difference from the colostrum of the cited prior art and the colostrum that they prepare using art recognized process steps. A colostrum product in a food will intrinically possess the property and/or characteritic of changing a subject's work capacity. It is therefore, the examiner's position that all three of the criteria for establishing a prima facie case of obviousness have been met and claims are rendered obvious over the newly cited prior art rejection herein.

Finally with respect to the Affidavit the argument that the currently submitted amendments and the calculation recited in the Affidavit show that the effect of administered IGF-1 on in vivo IGF-1 level in the human is minimal, is not deemed persuasive because the amount of change is unclear and hence any in vivo comparison is not clearly represented in the Affidavit. It is suggested that Applicants amend the claims to remove the term "significantly" and to further make the claims commensurate in scope with the calculations represented in the Affidavit.

All claims fail to be patentably distinguishable over the state of the art discussed above and previously cited on the PTO-892 and/or PTO-1449 Forms of record. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
November 25, 2007

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1657